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Dakin

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(54) **PARAVALVULAR LEAK OCCLUSION
DEVICE FOR SELF-EXPANDING HEART
VALVES**

A61B 17/1214; A61B 17/12145; A61B
17/1215; A61B 17/12154; A61B 17/12168;
A61B 17/12172; A61B 17/12177
USPC 604/96.01; 606/158, 191, 192, 194,
606/195, 198; 623/2.1–2.35
See application file for complete search history.

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patent is extended or adjusted under 35
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(2013.01); **A61B 17/12118** (2013.01); **A61F**
2/2418 (2013.01); **A61F 2002/077** (2013.01);
A61F 2250/0069 (2013.01)

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A61F 2/246; A61F 2220/0083; A61F
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2/89; A61F 2/90; A61F 2/915; A61F
2002/91508–2002/91591; A61B 17/12122;
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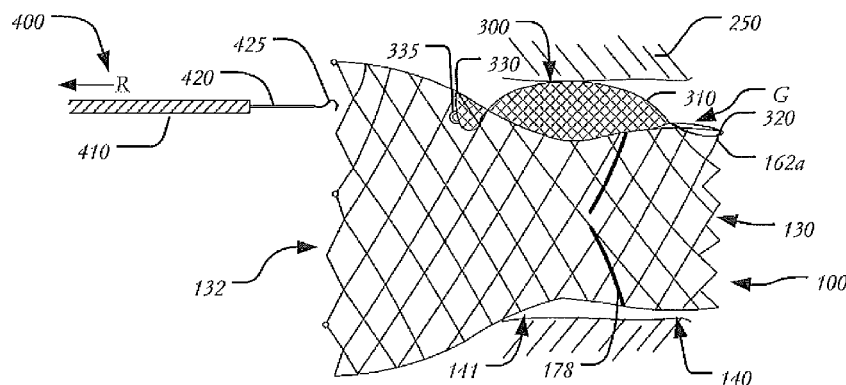
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ABSTRACT

An occluder for sealing gaps between a medical device and
adjacent body tissue includes an expandable body configured
to fill the gaps between the medical device and the body
tissue. The occluder includes a fastener at one end of the body
and adapted to couple to a first end of the medical device, and
an expandable disk at the other end of the body and adapted to
couple to the medical device at a position spaced from the first
end.

20 Claims, 9 Drawing Sheets



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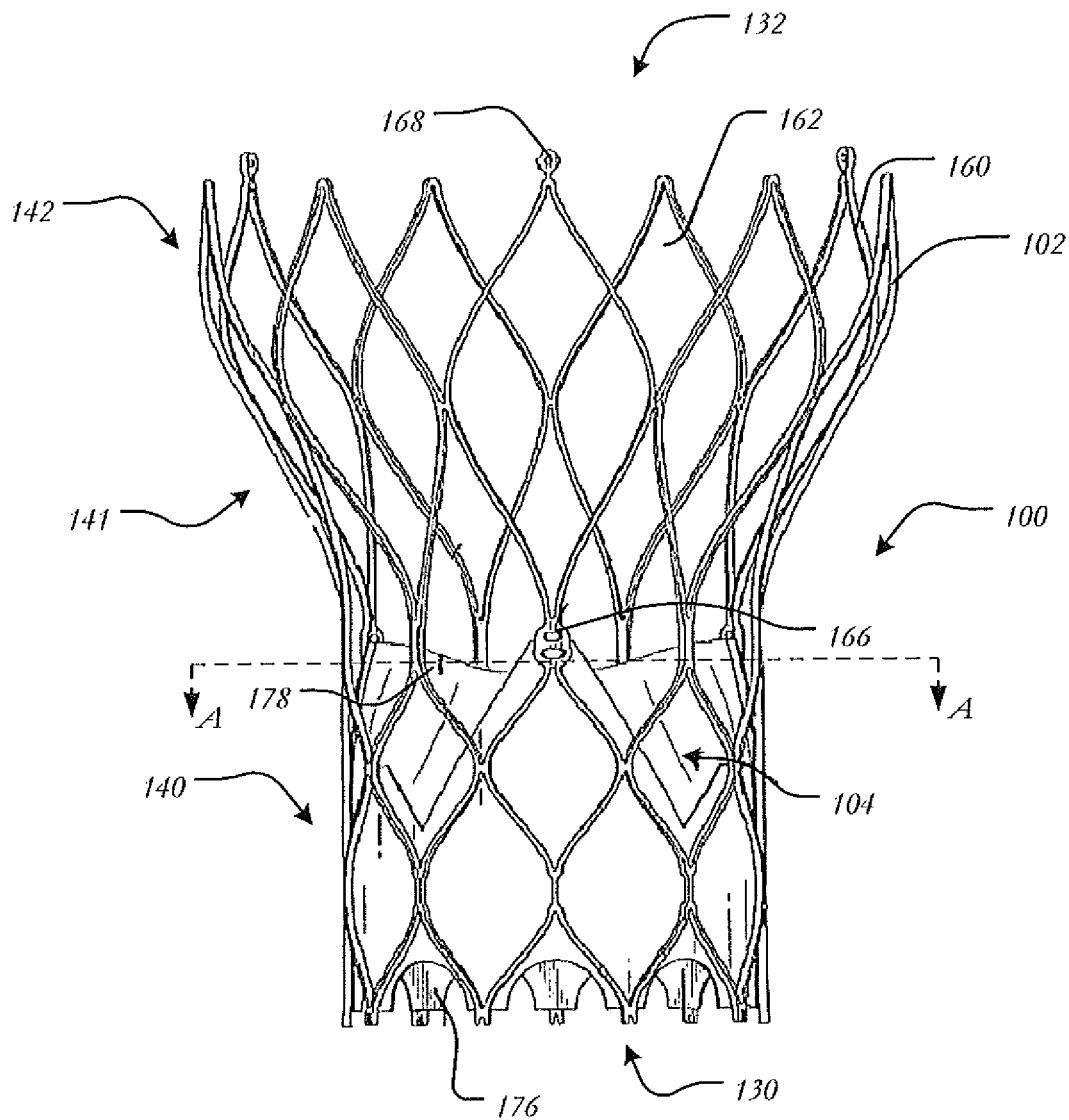


FIG. 1
(PRIOR ART)

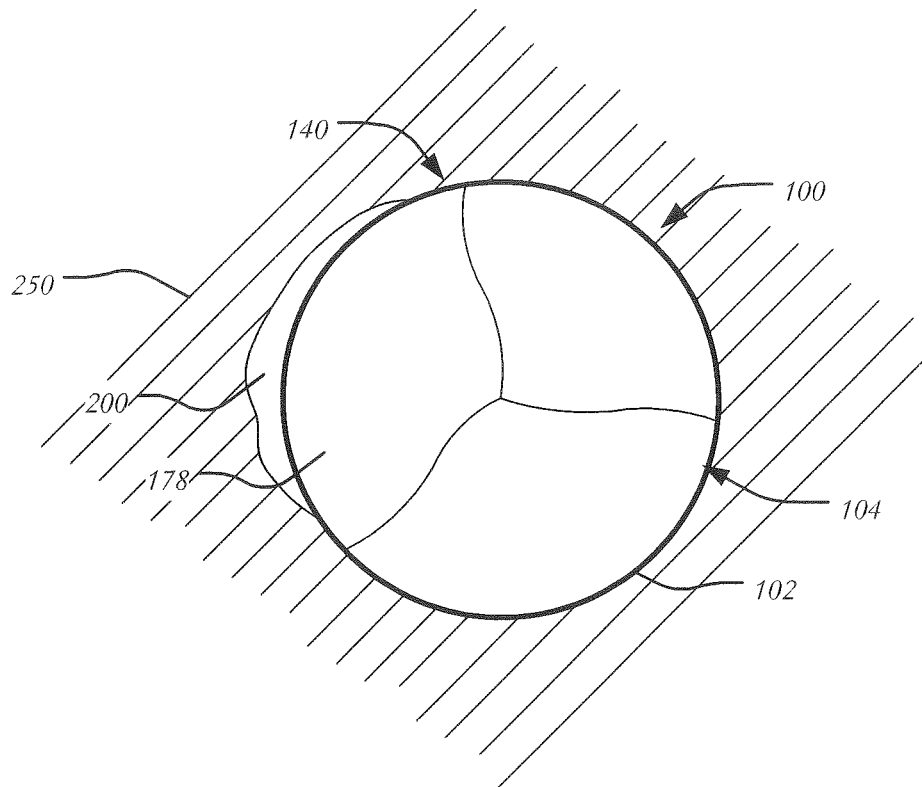


FIG. 2

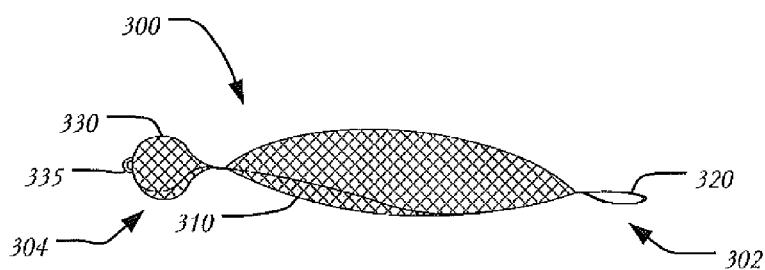


FIG. 3A

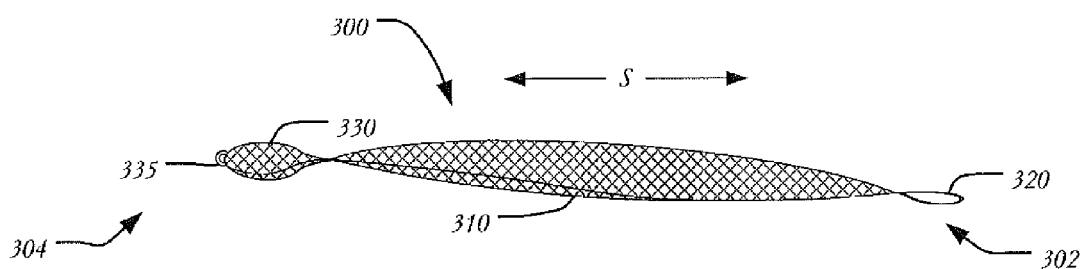


FIG. 3B

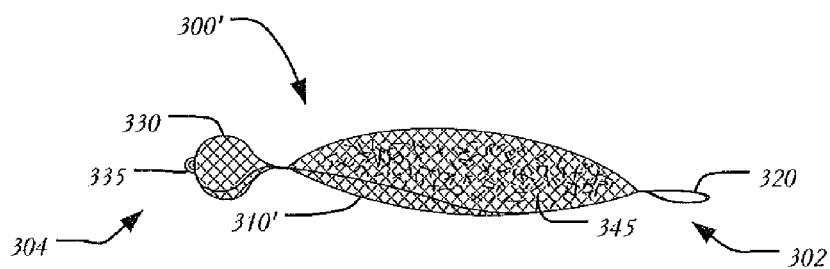


FIG. 3C

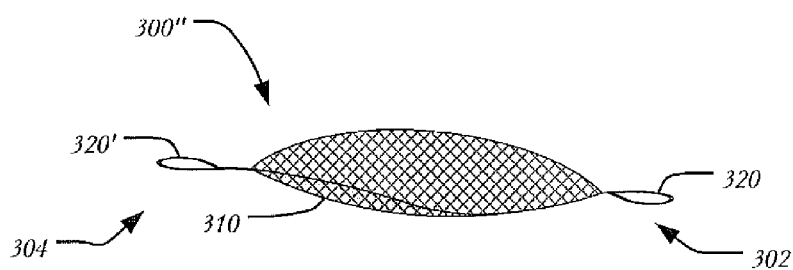


FIG. 3D

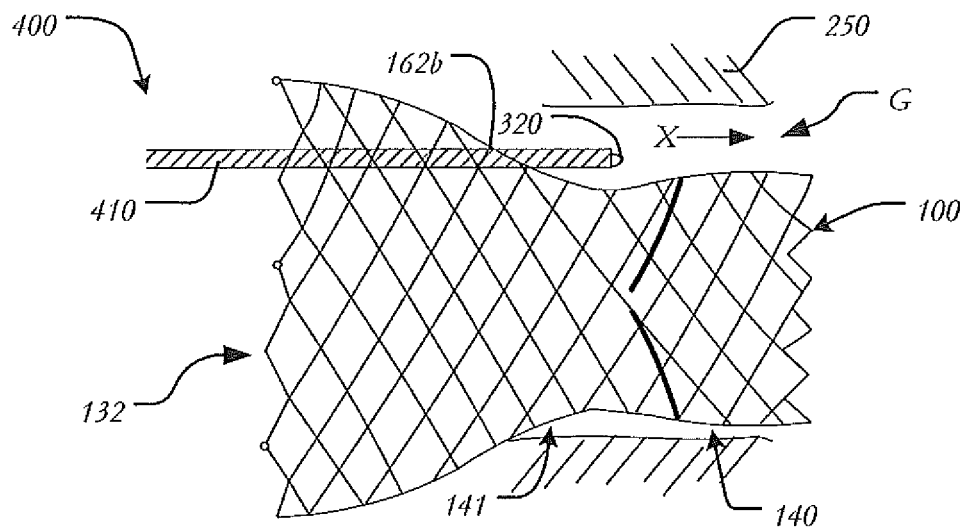


FIG. 4A

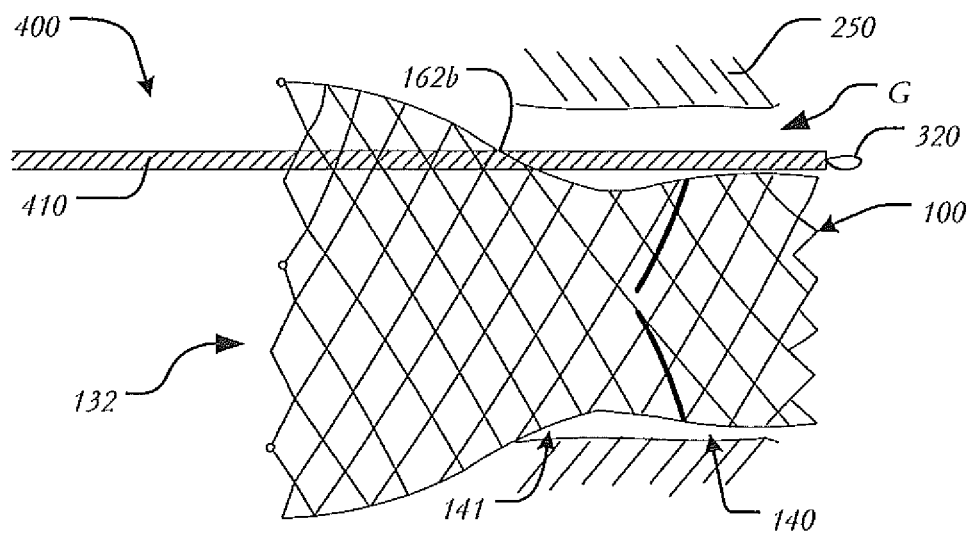


FIG. 4B

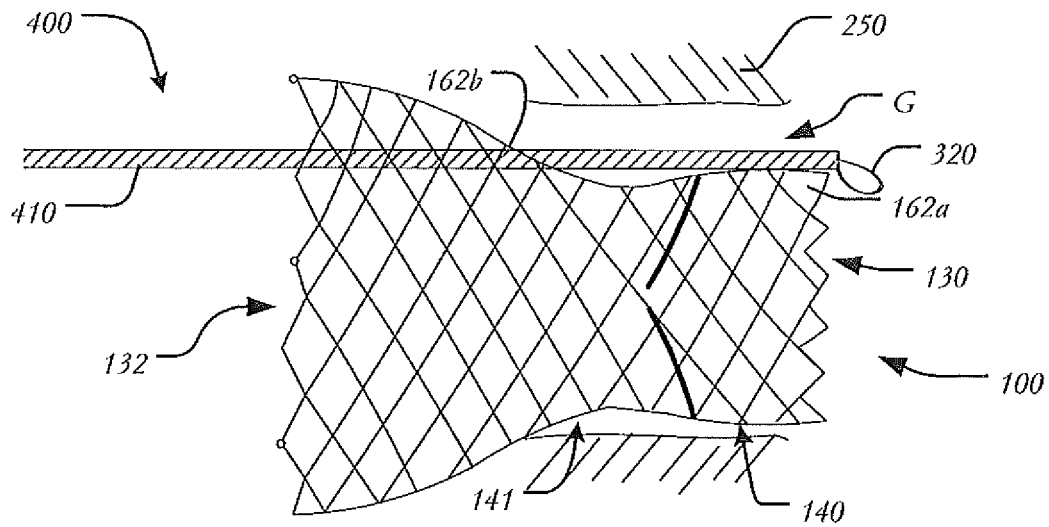


FIG. 4C

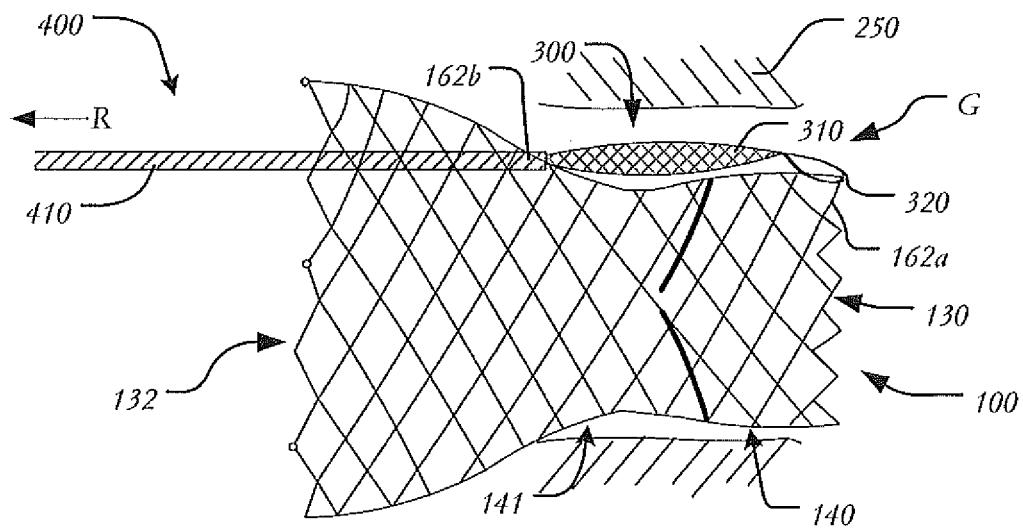


FIG. 4D

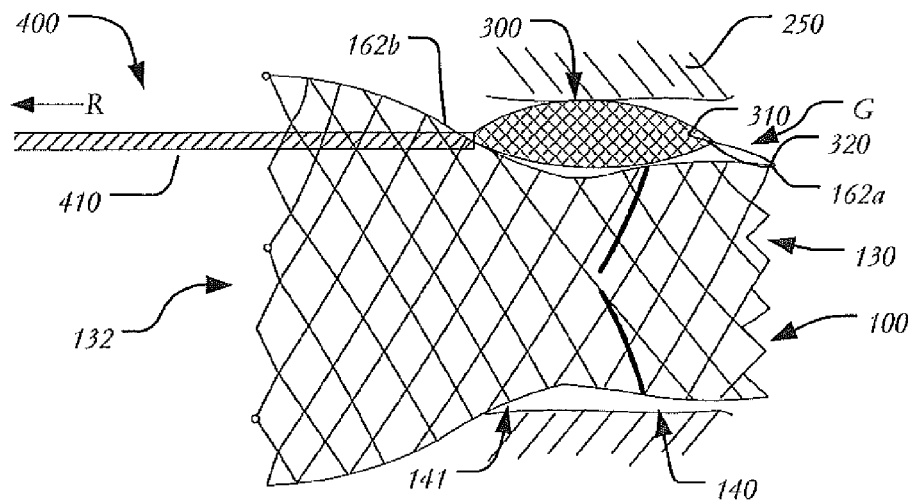


FIG. 4E

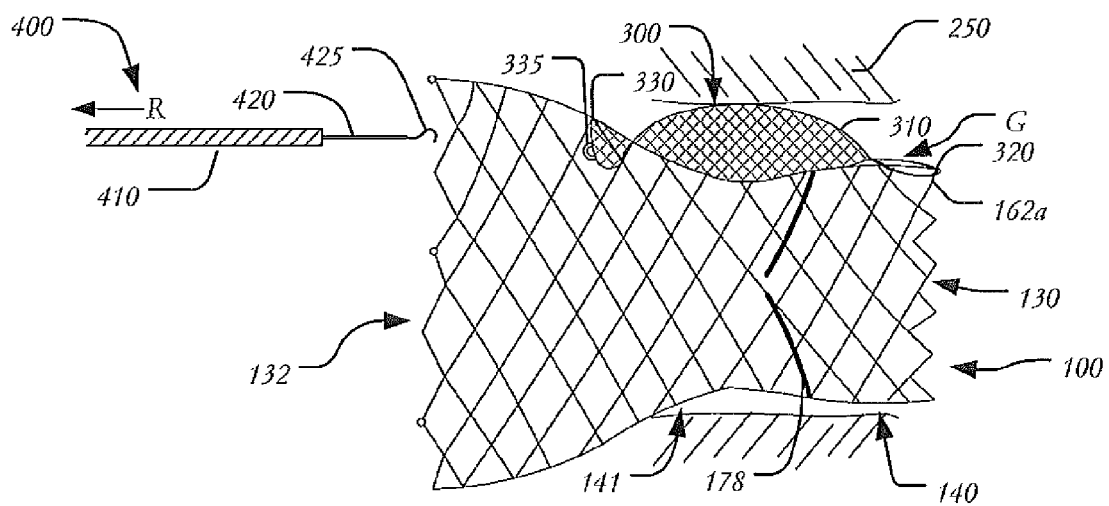
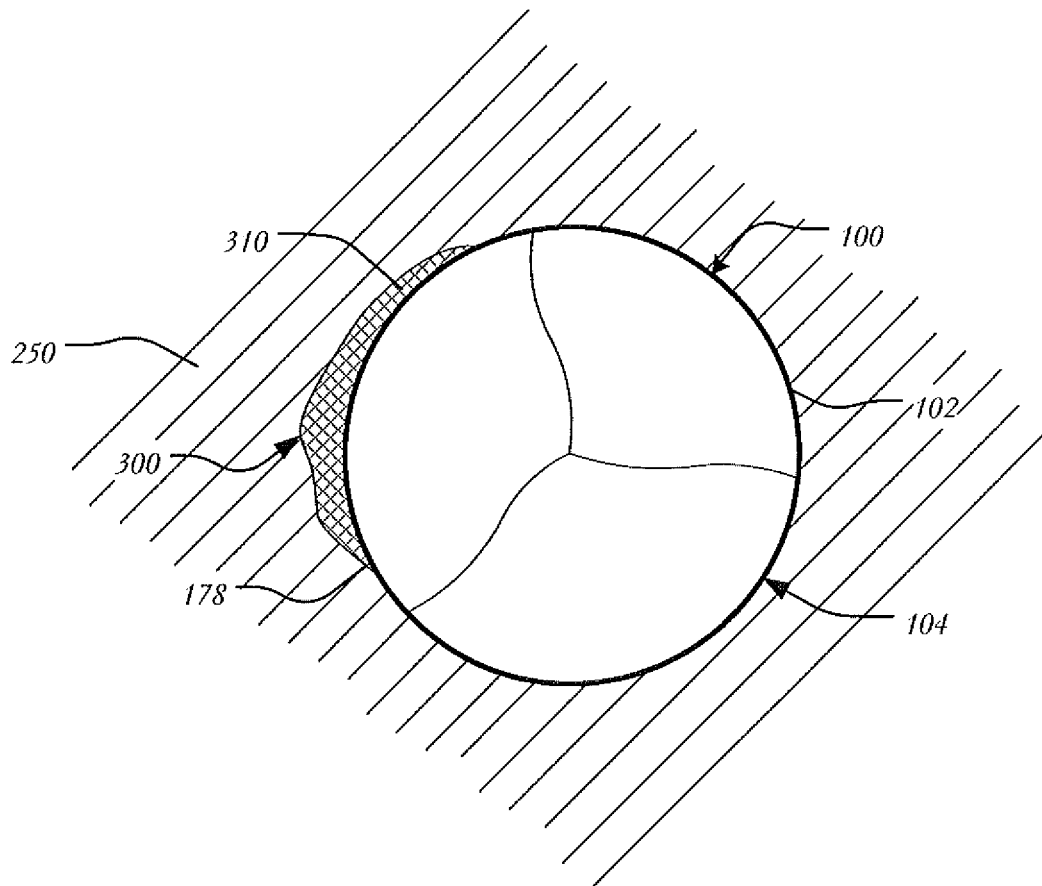
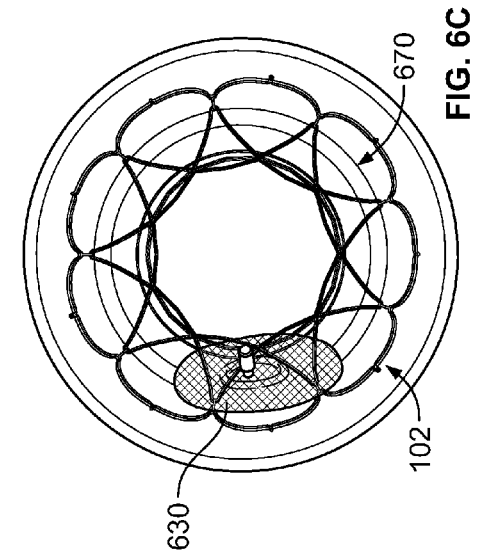
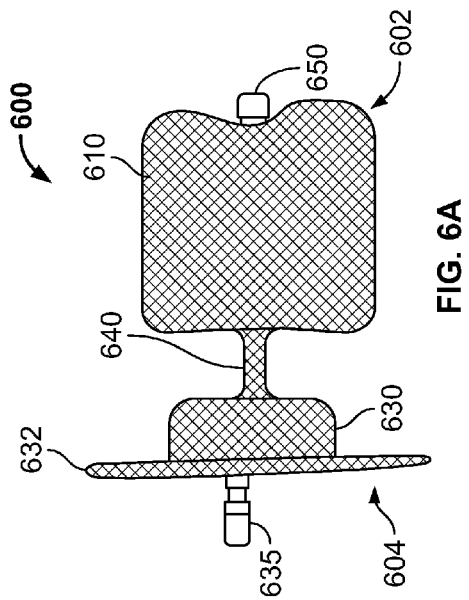
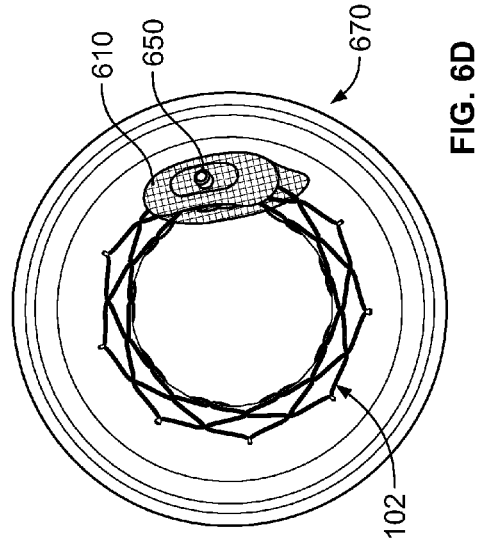
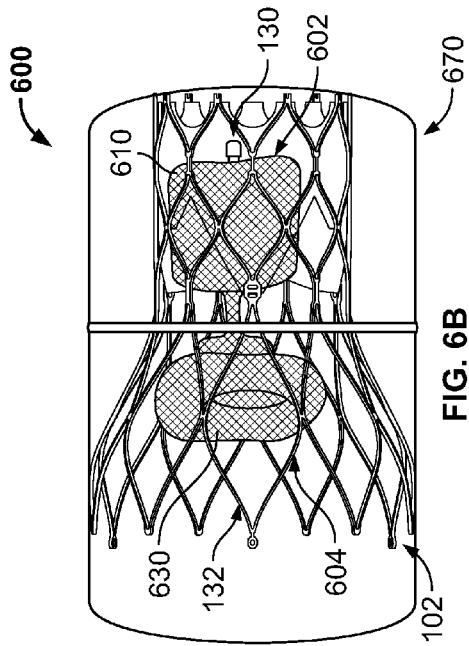


FIG. 4F

**FIG. 5**



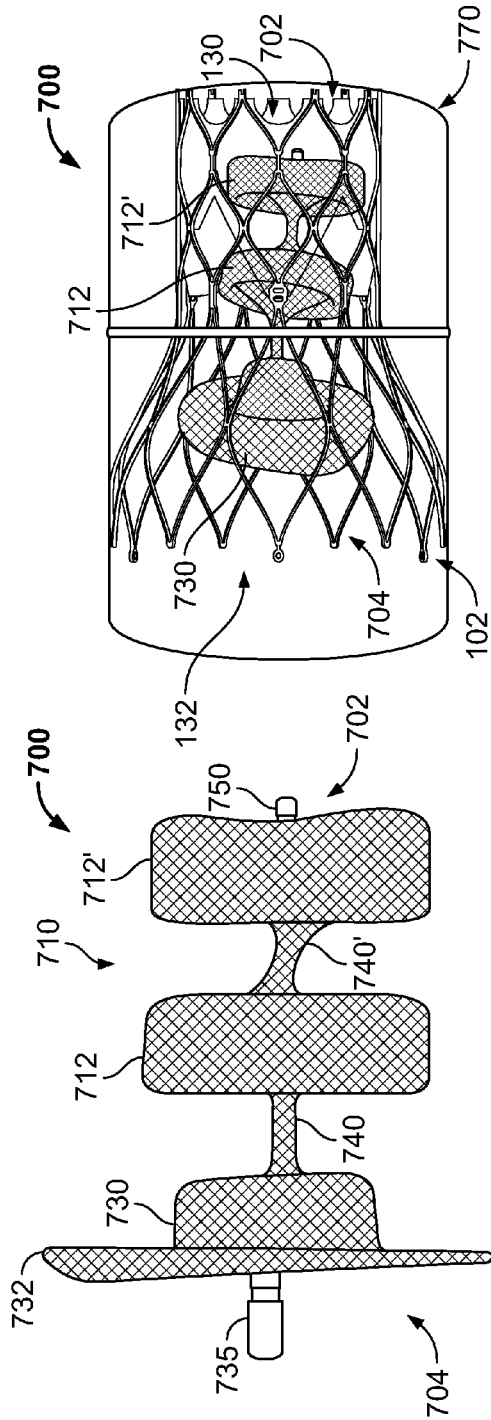


FIG. 7B

FIG. 7A

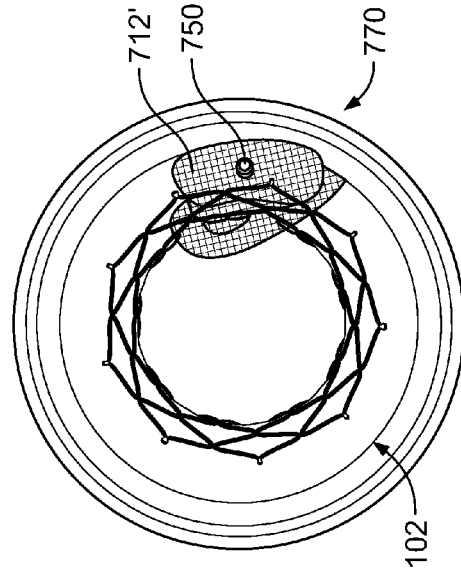


FIG. 7D

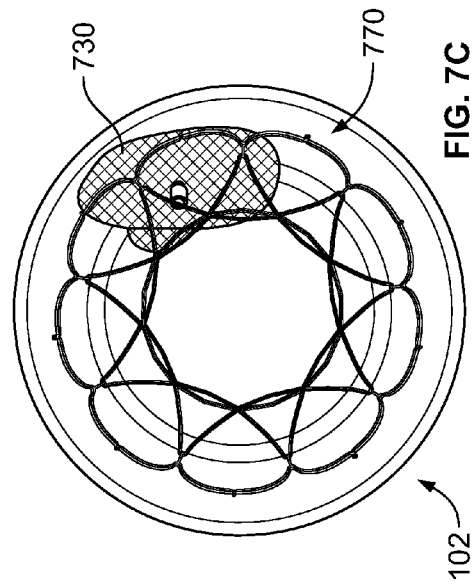


FIG. 7C

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PARAVALVULAR LEAK OCCLUSION DEVICE FOR SELF-EXPANDING HEART VALVES

BACKGROUND OF THE INVENTION

The present disclosure relates in general to heart valve replacement and, in particular, to collapsible prosthetic heart valves. More particularly, the present disclosure relates to devices and methods for positioning and sealing of collapsible prosthetic heart valves.

Prosthetic heart valves that are collapsible to a relatively small circumferential size can be delivered into a patient less invasively than valves that are not collapsible. For example, a collapsible valve may be delivered into a patient via a tube-like delivery apparatus such as a catheter, a trocar, a laparoscopic instrument, or the like. This collapsibility can avoid the need for a more invasive procedure such as full open-chest, open-heart surgery.

Collapsible prosthetic heart valves typically take the form of a valve structure mounted on a stent. There are two types of stents on which the valve structures are ordinarily mounted: a self-expanding stent or a balloon-expandable stent. To place such valves into a delivery apparatus and ultimately into a patient, the valve must first be collapsed or crimped to reduce its circumferential size.

When a collapsed prosthetic valve has reached the desired implant site in the patient (e.g., at or near the annulus of the patient's heart valve that is to be replaced by the prosthetic valve), the prosthetic valve can be deployed or released from the delivery apparatus and re-expanded to full operating size. For balloon-expandable valves, this generally involves releasing the entire valve, and then expanding a balloon positioned within the valve stent. For self-expanding valves, on the other hand, the stent automatically expands as the sheath covering the valve is withdrawn.

SUMMARY OF THE INVENTION

In some embodiments, an occluder device for occluding a gap between a medical device and adjacent body tissue includes an expandable body having a first end and a second end, a fastener coupled to the first end of the body, and an expandable disk coupled to the second end of the body.

In some embodiments, a method for occluding a gap between a prosthetic heart valve and adjacent body tissue includes delivering an occluder into the interior of the heart valve, the occluder having (i) an expandable body, (ii) a fastener coupled to one end of the body, and (iii) an expandable disk coupled to another end of the body. The occluder is advanced through a cell of the heart valve to the outside of the heart valve. The fastener is coupled to one end of the prosthetic heart valve and the expandable disk is coupled to the prosthetic heart valve at a position spaced from the one end.

BRIEF DESCRIPTION OF THE DRAWINGS

Various embodiments of the present disclosure are described herein with reference to the drawings, wherein:

FIG. 1 is a side elevational view of a conventional prosthetic heart valve;

FIG. 2 is a highly schematic cross-sectional view taken along line A-A of FIG. 1 and showing the prosthetic heart valve disposed within a native valve annulus;

FIG. 3A is a side view of a conformable occluder in accordance with one embodiment of the present disclosure;

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FIG. 3B is a side view of the conformable occluder of FIG. 3A after it has been stretched longitudinally;

FIG. 3C is a side view of a conformable occluder having a filler in accordance with another embodiment of the present invention;

FIG. 3D is a side view of a conformable occluder having two fasteners in accordance with another embodiment of the present invention;

FIGS. 4A-F illustrate the steps used to insert a conformable occluder to seal a prosthetic heart valve within a native valve annulus;

FIG. 5 is a highly schematic cross-sectional view showing a prosthetic heart valve disposed within a native valve annulus along with a conformable occluder in its fully expanded state;

FIG. 6A is a side view of a conformable occluder in accordance with another embodiment of the present disclosure;

FIGS. 6B-D are side, top and bottom views showing the use of the conformable occluder of FIG. 6A in vitro;

FIG. 7A is a side view of a conformable occluder in accordance with another embodiment of the present disclosure; and

FIGS. 7B-D are side, top and bottom views showing the use of the conformable occluder of FIG. 7A in vitro.

DETAILED DESCRIPTION

Despite the various improvements that have been made to the collapsible prosthetic heart valve delivery process, conventional devices suffer from some shortcomings. For example, with conventional self expanding valves, clinical success of the valve is dependent on accurate deployment and anchoring. Inaccurate deployment and anchoring of the valve increases risks, such as those associated with valve migration, which may cause severe complications and possibly death due to the obstruction of the left ventricular outflow tract. Inaccurate deployment and anchoring may also result in the leakage of blood between the implanted heart valve and the native valve annulus, commonly referred to as paravalvular leakage. This leakage enables blood flow from the aorta back into the left ventricle, reducing cardiac efficiency and putting a greater strain on the heart muscle. Additionally, calcification of the aortic valve may affect performance and the interaction between the implanted valve and the calcified tissue is believed to be relevant to leakage, as will be outlined below.

Moreover, anatomical variations between patients may require removal of a fully deployed heart valve from the patient if it appears that the valve is not functioning properly. Removing a fully deployed heart valve increases the length of the procedure and increases the risk of infection and/or damage to heart tissue. Thus, methods and devices are desirable that would reduce the likelihood of removal. Methods and devices are also desirable that would reduce the likelihood of valve leakage due to gaps formed between the implanted heart valve and patient tissue known as paravalvular leaks.

There therefore is a need for further improvements to the devices, systems, and methods for transcatheter delivery and positioning of collapsible prosthetic heart valves. Specifically, there is a need for further improvements to the devices, systems, and methods for accurately implanting a prosthetic heart valve. Among other advantages, the present disclosure may address one or more of these needs.

Various embodiments of the present invention will now be described with reference to the appended drawings. It is to be appreciated that these drawings depict only some embodiments of the invention and are therefore not to be considered limiting of its scope.

As used herein, the term “proximal,” when used in connection with a prosthetic heart valve, refers to the end of the heart valve closest to the heart when the heart valve is implanted in a patient, whereas the term “distal,” when used in connection with a prosthetic heart valve, refers to the end of the heart valve farthest from the heart when the heart valve is implanted in a patient. When used in connection with devices for delivering a prosthetic heart valve or other medical device into a patient, the terms “trailing” and “leading” are to be taken as relative to the user of the delivery devices. “Trailing” is to be understood as relatively close to the user, and “leading” is to be understood as relatively farther away from the user.

The leak occluders of the present invention may be used in connection with collapsible prosthetic heart valves. FIG. 1 shows one such collapsible stent-supported prosthetic heart valve **100** including a stent **102** and a valve assembly **104** as known in the art. The prosthetic heart valve **100** is designed to replace a native tricuspid valve of a patient, such as a native aortic valve. It should be noted that while the inventions herein are described predominately in connection with their use with a prosthetic aortic valve and a stent having a shape as illustrated in FIG. 1, the valve could be a bicuspid valve, such as the mitral valve, and the stent could have different shapes, such as a flared or conical annulus section, a less-bulbous aortic section, and the like, and a differently shaped transition section.

Prosthetic heart valve **100** will be described in more detail with reference to FIG. 1. Prosthetic heart valve **100** includes expandable stent **102** which may be formed from, for example, a shape memory material, such as the nickel-titanium alloy known as “Nitinol” or other suitable metals, and in particular, from those materials that are capable of self-expansion. Stent **102** extends from proximal or annulus end **130** to a distal or aortic end **132**, and includes annulus section **140** adjacent proximal end **130**, transition section **141** and aortic section **142** adjacent distal end **132**. Annulus section **140** has a relatively small cross-section in the expanded condition, while aortic section **142** has a relatively large cross-section in the expanded condition. Preferably, annulus section **140** is in the form of a cylinder having a substantially constant diameter along its length. Transition section **141** may taper outwardly from annulus section **140** to aortic section **142**. Each of the sections of stent **102** includes a plurality of struts **160** forming cells **162** connected to one another in one or more annular rows around the stent. For example, as shown in FIG. 1, annulus section **140** may have two annular rows of complete cells **162** and aortic section **142** and transition section **141** may each have one or more annular rows of partial cells **162**. Cells **162** in aortic section **142** may be larger than cells **162** in annulus section **140**. The larger cells in aortic section **142** better enable prosthetic valve **100** to be positioned in the native valve annulus without the stent structure interfering with blood flow to the coronary arteries.

Stent **102** may also include a plurality of commissure features **166** for attaching the commissure between two adjacent leaflets to stent **102**. As can be seen in FIG. 1, commissure features **166** may lie at the intersection of four cells **162**, two of the cells being adjacent one another in the same annular row, and the other two cells being in different annular rows and lying in end-to-end relationship. Preferably, commissure features **166** are positioned entirely within annulus section **140** or at the juncture of annulus section **140** and transition section **141**. Commissure features **166** may include one or more eyelets which facilitate the suturing of the leaflet commissure to the stent.

Stent **102** may include one or more retaining elements **168** at distal end **132** thereof, retaining elements **168** being sized

and shaped to cooperate with female retaining structures (not shown) provided on the deployment device. The engagement of retaining elements **168** with the female retaining structures on the deployment device helps maintain prosthetic heart valve **100** in assembled relationship with the deployment device, minimizes longitudinal movement of the prosthetic heart valve relative to the deployment device during unsheathing or resheathing procedures, and helps prevent rotation of the prosthetic heart valve relative to the deployment device as the deployment device is advanced to the target location and the heart valve deployed.

Prosthetic heart valve **100** includes valve assembly **104** preferably positioned in annulus section **140** of the stent **102** and secured to the stent. Valve assembly **104** includes cuff **176** and a plurality of leaflets **178** which collectively function as a one-way valve by coapting with one another. As a prosthetic aortic valve, valve **100** has three leaflets **178**, as well as three commissure features **166**. However, it will be appreciated that other prosthetic heart valves with which the leak occluders of the present invention may be used may have a greater or lesser number of leaflets **178** and commissure features **166**.

Although cuff **176** is shown in FIG. 1 as being disposed on the luminal or inner surface of annulus section **140**, it is contemplated that cuff **176** may be disposed on the abluminal or outer surface of annulus section **140** or may cover all or part of either or both of the luminal and abluminal surfaces. Both cuff **176** and leaflets **178** may be wholly or partly formed of any suitable biological material or polymer such as, for example, polytetrafluoroethylene (PTFE).

Prosthetic heart valve **100** may be used to replace a native aortic valve, a surgical heart valve or a heart valve that has undergone a surgical procedure. The prosthetic heart valve may be delivered to the desired site (e.g., near the native aortic annulus) using any suitable delivery device. During delivery, prosthetic heart valve **100** is disposed inside the delivery device in the collapsed condition. The delivery device may be introduced into a patient using a transfemoral, transapical, transseptal or any other percutaneous approach. Once the delivery device has reached the target site, the user may deploy prosthetic heart valve **100**. Upon deployment, prosthetic heart valve **100** expands so that annulus section **140** is in secure engagement within the native aortic annulus. When prosthetic heart valve **100** is properly positioned inside the heart, it works as a one-way valve, allowing blood to flow from the left ventricle of the heart to the aorta, and preventing blood from flowing in the opposite direction.

Problems may be encountered when implanting prosthetic heart valve **100**. For example, in certain procedures, collapsible valves may be implanted in a native valve annulus without first resecting the native valve leaflets. The collapsible valves may have critical clinical issues because of the nature of the stenotic leaflets that are left in place. Additionally, patients with uneven calcification, bi-cuspid aortic valve disease, and/or valve insufficiency cannot be treated well, if at all, with the current collapsible valve designs.

The reliance on unevenly calcified leaflets for proper valve placement and seating could lead to several problems, such as paravalvular (also known as perivalvular) leakage (PV leak), which can have severe adverse clinical outcomes. To reduce these adverse events, the optimal valve would anchor adequately and seal without the need for excessive radial force that could harm nearby anatomy and physiology.

FIG. 2 is a highly schematic cross-sectional illustration of prosthetic heart valve **100** disposed within native valve annulus **250**. As seen in the figure, annulus section **140** of the stent **102** has a substantially circular cross-section which is disposed within the non-circular native valve annulus **250**. At

certain locations around the perimeter of heart valve **100**, crescent-shaped gaps **200** form between heart valve **100** and native valve annulus **250**. Blood flowing through these gaps and past valve assembly **104** of prosthetic heart valve **100** can cause regurgitation and other inefficiencies which reduce cardiac performance. Such improper fitment may be due to sub-optimal native valve annulus geometry due, for example, to calcification of native valve annulus **250** or to unresected native leaflets.

FIGS. **3A** and **3B** illustrate one embodiment of conformable occluder **300** intended to fill irregularities between heart valve **100** and native valve annulus **250** shown in FIG. **2**. As will be described in more detail below, conformable occluder **300** allows for superior sealing between the perimeter of heart valve **100** and native valve annulus **250** while affording a low radial outward force. FIG. **3A**, shows conformable occluder **300** in a relaxed and expanded configuration while FIG. **3B** shows conformable occluder **300** in a stretched and partially elongated configuration. Conformable occluder **300** has a leading end **302** and a trailing end **304**, and may generally include body **310**, fastener **320**, and disk **330**.

Body **310** may be a metallic structure that may be longitudinally stretched in the direction of arrows **S** from a relaxed condition shown in FIG. **3A** to a stretched condition shown in FIG. **3B**. In the relaxed condition, body **310** may have a cross-section that is greater in size than it is in the stretched condition. Thus, body **310** of conformable occluder **300** may be flexible and capable of contracting in the radial direction when a force is applied thereto to conform to the shape of the annulus in which it will be implanted. Moreover, the ability of body **310** to longitudinally stretch in the direction of arrow **S** will allow the occluder to be delivered through a small diameter catheter and to be secured between two attachment points as will be seen below with reference to FIGS. **4A-4F**.

Occluder **300** may be formed from a tubular section of braided fabric comprising a plurality of braided strands. The strands forming the braid may have a predetermined relative orientation with respect to one another (e.g., a helical braid). The ends of the strands may be located at leading end **302** and trailing end **304** and affixed to prevent unraveling by any suitable means such as solder, braze, weld, coat, glue, clamp, tie, or clamp. Moreover, occluder **300** may comprise a plurality of layers of braided fabric and/or other occluding material (e.g. see filler **345** in FIG. **3C**) such that occluder **300** is capable of at least partially inhibiting blood flow therethrough in order to facilitate the formation of thrombus and epithelialization.

Occluder **300** may be formed, for example, of a braided fabric mesh of a shape-memory material, of a super-elastic material, of a bio-compatible polymer, or of another material that is capable of collapsing and expanding. In the embodiments depicted in FIGS. **3A-3C**, occluder **300** comprises a braided metal fabric that is both resilient and capable of heat treatment to substantially set a desired preset shape (e.g. the relaxed configuration shown in FIG. **3A**). One class of materials which meets these qualifications is shape memory alloys. One example of a shape memory alloy is Nitinol. It is also understood occluder **300** may comprise various materials other than Nitinol that have elastic and/or memory properties, such as spring stainless steel, trade named alloys such as Elgiloy®, Hastelloy®, CoCrNi alloys (e.g., trade name Phynox), MP35N®, CoCrMo alloys, or a mixture of metal and polymer fibers. Depending on the individual material selected, strand diameter, number of strands, and pitch may be altered to achieve the desired properties of occluder **300**.

As further described below, body **310** may be collapsed during delivery into the patient and re-expanded after delivery

to occlude gaps between a prosthetic heart valve and the native valve annulus to one side of the valve. While body **310** is shown in FIG. **3A** as having an elliptical longitudinal cross-section in the expanded condition, it will be understood that the body may be constructed with various shapes and/or sizes. For example, body **310** may have a circular, oval, polygonal, square, diamond, triangular or other shape in longitudinal cross-section when expanded. Body **310** may also include two or more segments. Additionally, body **310** may be formed of multiple layers of braid to decrease occlusion time.

Body **310** may be connected to fastener **320** at leading end **302** of conformable occluder **300**. Fastener **320** may be formed of a suture, polymeric fiber, metallic filament, such as a flexible stranded stainless steel cable or loop of nitinol wire, or other suitable material, and may be configured to secure conformable occluder **300** to prosthetic heart valve **100** as will be described in greater detail below. Though fastener **320** is shown in FIG. **3A** as a loop, it will be understood that a simple hook, clasp or other similar structure capable of grasping, clipping, or hooking conformable occluder **300** to strut **160** of prosthetic heart valve **100** may be used.

Body **310** may further be coupled to disk **330** at trailing end **304** of conformable occluder **300**. In the depicted embodiment, body **310** is coupled to disk **330** by a small diameter waist. Disk **330** may be an ovalar or spherical body sized to couple conformable occluder **300** to a cell of a prosthetic heart valve. Specifically, disk **330** may be sized larger than cell **162** of stent **102** such that it is incapable of passing through the cell (see FIG. **1**). Disk **330** may be formed of the same material as body **310** or from a different material. For example, disk **330** may be formed of a braided nitinol mesh or other shape-memory mesh. It is also contemplated that disk **330** may be constructed from a bio-compatible polymer material. Disk **330** may include a lip having a greater cross-sectional dimension than disk **330**. Female component **335** connected to disk **330** at trailing edge **335** may be used to couple conformable occluder **300** to a delivery device to position and deliver conformable occluder **300**. Female component **335** may include an internally threaded screw attachment, a ring, or any other suitable means for coupling with a delivery device.

In one example, as shown in FIG. **3C**, body **310'** may be hollow and may be at least partially filled with filler **345** of a fabric or fibers of materials that are intertwined within the mesh of conformable occluder **300'** to assist with sealing, occlusion and healing. For example, body **310'** may include filler **345** of polyester threads or polyester fabric, as well as any suitable fiber material to increase density and/or promote tissue growth. Filler **345** may also be in the form of a foam material, such as a closed cell sponge. The density of body **310'** may be such that it impedes the flow of blood through it. Inclusion of filler **345** in body **310'** may speed occlusion time for conformable occluder **300'**.

In an alternative embodiment, shown in FIG. **3D**, occluder **300''** has leading end **302** and trailing end **304**, and may generally include body **310** extending entirely from leading end **302** to the trailing end **304**. As seen in FIG. **3D**, occluder **300''** includes first fastener **320** at leading end **302**. Instead of a disk on the opposite end (see disk **335** in FIGS. **3A-3C**), occluder **300''** includes second fastener **320'** disposed near trailing end **304**. In this embodiment, occluder **300''** may be coupled to select struts **160** of stent **102** via first and second fasteners **320,320'** without the need for disk **335**.

FIGS. **4A-F** illustrate the steps used to insert conformable occluder **300** (or conformable occluder **300'** or conformable occluder **300''**) to seal heart valve **100** within native valve annulus **250**. As seen in FIG. **4A**, heart valve **100** has been

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implanted in a patient with annulus portion **140** thereof positioned in native valve annulus **250**. Gap **G** may be formed between heart valve **100** and native valve annulus **250** to one side of heart valve **100**.

As an initial step to seal gap **G**, conformable occluder **300** may be disposed within delivery system **400** (FIG. 4A) in a collapsed condition, such as the stretched or elongated configuration shown in FIG. 3B. Delivery system **400** may include outer sheath **410** and inner wire **420** having male component **425**. Male component **425** may include a conventional screw attachment, a terminal hook or other suitable structure for mating with female component **335**. Male component **425** is configured to couple with female component **335** of conformable occluder **300** (elements shown uncoupled in FIG. 4F). Outer sheath **410** is slidable relative to inner wire **420**. Delivery system **400** may be inserted into the patient and advanced toward the implanted heart valve **100** in the direction of arrow **X**. As it reaches heart valve **100**, delivery system **400** may be advanced into the heart valve **100** at aortic end **132** and out therefrom through cell **162b** in transition section **141** (shown in FIG. 4A). Delivery system **400** may then be further advanced through gap **G** toward annulus end **140** of implanted heart valve **100**, as shown in FIG. 4B. If heart valve **100** or delivery system **400** includes echogenic materials, such materials may be used to guide delivery system **400** to the appropriate position using the assistance of three-dimensional echocardiography to visualize heart valve **100** within the patient.

Once delivery system **400** has reached the desired site of sealing (e.g. gap **G**) as shown in FIG. 4C, outer sheath **410** may be retracted slightly in the direction of arrow **R** (toward the trailing end of delivery system **400**) to expose fastener **320** (shown in FIG. 4D). Conformable occluder **300** remains coupled to inner wire **420** at this stage and trailing edge **304** of occluder **300** remains housed by delivery system **400**.

Delivery system **400** may be manipulated by gently twisting and/or tilting delivery system **400** to position fastener **320** over the apex of cell **162a** at annulus end **130** of heart valve **100**. Once fastener **320** has latched onto or been looped around apex of cell **162a**, outer sheath **410** may be further retracted in the direction of arrow **R** to expose body **310** of conformable occluder **300**. As outer sheath **410** is further retracted, more of occluder body **310** is exposed and occluder **300** expands within the gap **G** between heart valve **100** and native valve annulus **250** (FIGS. 4D and 4E). As seen in FIGS. 4D-4F, body **310** is positioned parallel to annulus section **140** and transition section **141**. In this intermediate stage of deployment, body **310** has expanded to its relaxed state and contacted the walls of native valve annulus **250**, and substantially fills gap **G**.

Outer sheath **410** may then be fully retracted to expose disk **330** and allow it to expand near cell **162b**. In the depicted embodiment, disk **330** is located on the interior of heart valve **100**, although other in other embodiments, disk **330** is located on the exterior of heart valve **100**. In either instance, disk **330** is spaced away from valve assembly **104** so as not to impede normal leaflet **178** function. Disk **330** then expands to a size small enough for disk **330** to project partially out of or into cell **162b**, but remains too large to pass through that cell. The interference of disk **330** with cell **162b** creates a second attachment region for conformable occluder **300**. Thus, conformable occluder **300** is stretched between the two attachment regions—the interference between disk **330** and cell **162b** and the connection between fastener **320** and cell **162a**. Fastener **320** prevents occluder **300** from migrating into the aorta, while disk **330** prevents occluder **300** from migrating back into the heart. Alternatively, in embodiments having two

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fasteners instead of disk **330** such as that shown in FIG. 3D, first fastener **320** may be coupled to the apex of cell **162a**, while second fastener **320'** may be likewise coupled over the apex of a cell at the aortic end **132** of stent **100**.

Male component **425** may be disconnected from female component **335** by manipulating (e.g., rotating) wire **420**. Alternatively, inner wire **420** may comprise a suture tied to female component **335**, and the suture may be simply cut to release conformable occluder **300** from delivery system **400**. In another example, male and female components may be threaded and delivery system **400** may be twisted relative to occluder **300** to decouple the two from one another. Accordingly, many mating solutions between delivery system **400** and occluder **300** would serve the intended purpose for deployment of occluder **300**. FIG. 4F illustrates heart valve **100** in its fully expanded state with conformable occluder **300** fully filling the gap **G** between heart valve **100** and native valve annulus **250**. Delivery system **400** may then be withdrawn in the direction of arrow **R** and removed from the patient, leaving conformable occluder **300** in place to seal valve **100** within native valve annulus **250**.

FIG. 5 is a highly schematic cross-sectional view showing conformable occluder **300** in its relaxed state with body **310** fully radially expanded to fill crescent-shaped gap **200** shown in FIG. 2. The mesh of conformable occluder **300** may be capable of promoting tissue growth between heart valve **100** and native valve annulus **250**. For example, conformable occluder **300** may be treated with a biological or chemical agent to promote tissue growth on the conformable occluder, further sealing the heart valve within the native valve annulus. Alternatively, conformable occluder **300** may be sufficiently dense through the use of polyester fibers or polyester fabric to adequately seal the heart valve without the need for major tissue growth throughout gap **G**. Occluder **300** may also be double-layered and/or may include tighter braiding to more quickly occlude the space between heart valve **100** and native valve annulus **250**. When conformable occluder **300** is functioning properly, heart valve **100** will be adequately sealed within native valve annulus **250** so that blood flows through valve assembly **104** and passing through leaflets **108**, while limiting or at least reducing blood flow through any gaps formed between heart valve **100** and native valve annulus **250**.

FIG. 6A illustrates another embodiment of conformable occluder **600**. Conformable occluder **600** extends between leading end **602** and trailing end **604**, and may generally include a tubular body **610** and disk **630**. Disk **630** includes an enlarged outer rim **632** and is coupled to connector **635** for mating with a delivery system (not shown). As seen in FIG. 6A, reduced diameter neck portion **640** connects body **610** to disk **630**. A fastener (not shown) may be attached to joint **650** at leading end **602** to connect occluder **600** to an apex of a cell **162** as described above with reference to FIGS. 4A-4F.

FIGS. 6B-D are side, top and bottom end views illustrating the use of occluder **600**. Specifically, FIG. 6B shows a side view of the system while FIG. 6C illustrates a top view (e.g., as seen from aortic end **132** of stent **102**) and FIG. 6D illustrates a bottom view (e.g., as seen from annulus end **130** of stent **102**). In these figures, container **670** approximates the native valve annulus and stent **102** is disposed therein to simulate a prosthetic heart valve **100**. A valve assembly is not shown attached to the stent **102** for the sake of clarity. As seen in FIGS. 6B-D occluder **600** is coupled to stent **102** and shown to fill a gap between stent **102** and the native valve annulus, approximated by the walls of container **670**. Specifically, disk **630** is shown disposed within the interior of stent **102** (FIG. 6C) and body **610** is disposed outside of stent **102**

(FIG. 6D). Though a fastener is not shown, it will be understood that a fastener may attach to joint **650** and couple leading end **602** of occluder **600** to an apex of a cell at annulus end **130** of stent **102**. Occluder **600** may be delivered and positioned in a manner similar to that described above with reference to FIGS. 4A-F.

FIG. 7A illustrates another embodiment of conformable occluder **700**. Conformable occluder **700** extends between leading end **702** and trailing end **704**, and may generally include a body **710** formed of two body segments **712,712'**, and disk **730**. Though occluder **700** is shown having two segments **712,712'** it will be understood that three or more segments may be employed in constructing occluder **700**. In some instances, it may be helpful to use multiples segments **712,712'** as opposed to a single unitary body to improve occlusion. For example, first segment **712** may expand to a small radius, while a second segment **712'** may expand to a larger radius to accommodate a non-uniform native valve annulus and fill multiple gaps at varying longitudinal extents.

Disk **730** includes an enlarged outer rim **732** and is coupled to connector **735** for mating with a delivery system (not shown). As seen in FIG. 7A, two reduced diameter neck portions **740,740'** connect body disk **730** to first segment **712** and first segment **712** to second segment **712'**, respectively. A fastener (not shown) may be attached to joint **750** at leading end **702** to connect occluder **700** to an apex of a cell **162** as described above with reference to FIGS. 4A-F.

FIGS. 7B-D are side, top and bottom end views illustrating the use of occluder **700** within an approximating container **770** as described above with reference to FIGS. 6B-6D. As seen in FIGS. 7B-D occluder **700** is coupled to stent **102** and shown to fill a gap between stent **102** and the native valve annulus, approximated by the walls of container **770**. Specifically, disk **730** is shown disposed within the interior of stent **102** (FIG. 6C) and segments **712,712'** are disposed outside of stent **102** (FIG. 6D). Though a fastener is not shown, it will be understood that a fastener may attach to joint **750** to couple leading end **702** of occluder **700** to an apex of a cell at annulus end **130** of stent **102**. Occluder **700** may be delivered and positioned in a manner similar to that described above with reference to FIGS. 4A-F.

While the inventions herein have been described for use in connection with heart valve stents having a particular shape, the stent could have different shapes, such as a flared or conical annulus section, a less-bulbous aortic section, and the like, and a differently shaped transition section. Additionally, though conformable occluder **300** has been described in connection with expandable transcatheter aortic valve replacement, it may also be used in connection with surgical valves, sutureless valves and other devices in which it is desirable to create a seal between the periphery of the device and the adjacent body tissue. Additionally, though the deployment of occluder **300** has been described using delivery system **400** that deploys fastener **320** first, followed by body **310** and finally disk **330**, it will be understood that, through a different delivery approach, such as, for example, a transapical route, disk **330** may be deployed first, followed by body **310** and then fastener **320**.

It will also be understood that while the preceding disclosure has illustrated the use of a single occluder to fill gaps to one side of a prosthetic heart valve, it will be understood that multiple occluders may be deployed around the perimeter of a heart valve. Such occluders may be delivered successively to each gap formed between the prosthetic heart valve and the native valve annulus. Conversely, multiple occluders may be delivered simultaneously using a large single outer sheath having two or more male components or other connectors.

Additionally, multiple occluders may be simultaneously deployed by using multiple delivery systems each having a male component or other connector.

Moreover, although the disclosure herein has been described with reference to particular embodiments, it is to be understood that these embodiments are merely illustrative of the principles and applications of the present disclosure. It is therefore to be understood that numerous modifications may be made to the illustrative embodiments and that other arrangements may be devised without departing from the spirit and scope of the present disclosure as defined by the appended claims.

For examples, the occluder may be deployed for use with a prosthetic heart valve having a collapsible and expandable stent forming cells, and a valve assembly disposed in the stent for controlling the flow of blood through the stent. The disk is expandable from a collapsed configuration to a relaxed configuration, the disk in the relaxed configuration having a size larger than the size of at least some of the cells of the stent. The stent may include a plurality of struts and the fastener is coupleable to at least one of the plurality of the struts. The body may include at least one of a metallic mesh or a shape-memory material. The body may have an elliptical longitudinal cross-section. The body may include a metal mesh and polyester fiber intertwined with the metal mesh to increase the density of the body. The fastener may include a loop for coupling to the medical device. The disk may include at least one of a metallic mesh or a shape-memory material.

The device may also include a female component or other connected attached to the disk for coupling to a delivery device. The body may include an agent for promoting tissue growth. A system for occluding a gap between a medical device and adjacent body tissue may include the occluder and a delivery system including an outer sheath, an inner wire disposed within and translatable with respect to the outer sheath, and a male component or other connector attached to the inner wire, the male component or other connector being configured to couple the inner wire to the expandable disk of the occluder. The outer sheath may be adapted to house the occluder in a contracted configuration, the medical device is a prosthetic heart valve having a collapsible and expandable stent forming cells and a valve assembly disposed in the stent for controlling the flow of blood through the stent, and the outer sheath is sized to pass through a cell of the expandable stent.

In the methods described above, the fastener may be a loop and the step of coupling the fastener may include positioning the loop around an apex of a cell at the one end of the prosthetic heart valve. The body may have a substantially elliptical longitudinal cross-section in an expanded condition.

It will be appreciated that the various dependent claims and the features set forth therein can be combined in different ways than presented in the initial claims. It will also be appreciated that the features described in connection with individual embodiments may be shared with others of the described embodiments.

The invention claimed is:

1. A system for replacing native valve function, the system comprising:

a prosthetic heart valve having a collapsible and expandable stent forming cells, the stent having a plurality of sections including an annulus section, a transition section and an aortic section, and a valve assembly disposed in the stent; and

an occluder device comprising an expandable body having a first end and a second end, a fastener coupled to the first

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end of the body and to a selected strut of the stent at a first position on the annulus section of the stent, and an expandable disk coupled to the second end of the body and passing through a cell of the stent to couple the occluder device to the stent at a second position in a section other than the annulus section.

2. The system of claim 1, wherein the disk is expandable from a collapsed configuration to a relaxed configuration.

3. The system of claim 2, wherein the disk in the relaxed configuration has a size larger than the size of at least some of the cells of the stent.

4. The system of claim 1, wherein the stent includes a plurality of struts and the fastener is coupleable to at least one of the plurality of the struts.

5. The system of claim 1, wherein the body includes at least one of a metallic mesh or a shape-memory material.

6. The system of claim 1, wherein the body has an elliptical longitudinal cross-section.

7. The system of claim 1, wherein the body includes a metal mesh and polyester fiber intertwined with the metal mesh.

8. The system of claim 1, wherein the disk includes at least one of a metallic mesh or a shape-memory material.

9. The system of claim 1, further comprising a connector attached to the disk for coupling to a delivery device.

10. The system of claim 1, wherein the body includes multiple segments, each segment being capable of independent radial expansion from the other segments.

11. The system of claim 1, further comprising:

a delivery system including an outer sheath, an inner wire disposed within and translatable with respect to the outer sheath, and a connector attached to the inner wire, the connector being configured to couple the inner wire to the expandable disk of the occluder device.

12. The system of claim 11, wherein the outer sheath is adapted to house the occluder device in a contracted configuration, and the outer sheath is sized to pass through a cell of the expandable stent.

13. The system of claim 1, wherein the annulus section has a first diameter, the transition section has a second diameter, the first diameter being different than the second diameter, and the expandable disk passes through the cell of the stent in the transition section.

14. The system of claim 1, wherein the expandable body is entirely disposed between the fastener and the expandable disk.

15. A system for replacing native valve function, the system comprising:

a prosthetic heart valve having a collapsible and expandable stent forming cells, and a valve assembly disposed in the stent; and

an occluder device comprising an expandable body having a first end and a second end, the first end and the second

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end being disposed on opposite ends of the body, a fastener extending in a first direction and coupled to the first end of the body, the fastener capable of latching onto an apex of a cell at a first position, and an expandable disk extending in a second direction, opposite the first direction, and coupled to the second end of the body, the expandable disk passing through a cell of the stent to couple the occluder device to the stent at a second position.

16. A method for occluding a gap between a prosthetic heart valve and adjacent body tissue, the method comprising: providing:

(1) a prosthetic heart valve having a collapsible and expandable stent forming cells, the stent having a plurality of sections including an annulus section, a transition section and an aortic section, and a valve assembly disposed in the stent; and

(2) an occluder device comprising an expandable body having a first end and a second end, a fastener coupled to the first end of the body and to a selected strut of the stent at a first position on the annulus section of the stent, and an expandable disk coupled to the second end of the body and passing through a cell of the stent to couple the occluder device to the stent at a second position in a section other than the annulus section;

delivering an occluder into an interior of the heart valve, the occluder including (i) an expandable body, (ii) a fastener coupled to one end of the body, and (iii) an expandable disk coupled to another end of the body;

advancing the occluder through a cell of the prosthetic heart valve to an outside of the heart prosthetic valve; coupling the fastener to one end of the prosthetic heart valve; and

coupling the expandable disk to the prosthetic heart valve at a position spaced from the one end.

17. The method of claim 16, wherein the fastener is a loop and the step of coupling the fastener includes positioning the loop around an apex of a cell at the one end of the prosthetic heart valve.

18. The method of claim 16, wherein the disk in the relaxed configuration has a size larger than the size of at least one of the cells of the stent, and the step of coupling the disk includes disposing the disk on the outside of the at least one cell so that the disk cannot pass therethrough.

19. The method of claim 16, wherein delivering the occluder comprises disposing the occluder within a delivery system and advancing the delivery system into an interior of the prosthetic heart valve.

20. The method of claim 19, further comprising the step of coupling the expandable disk to an inner wire of the delivery system.

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